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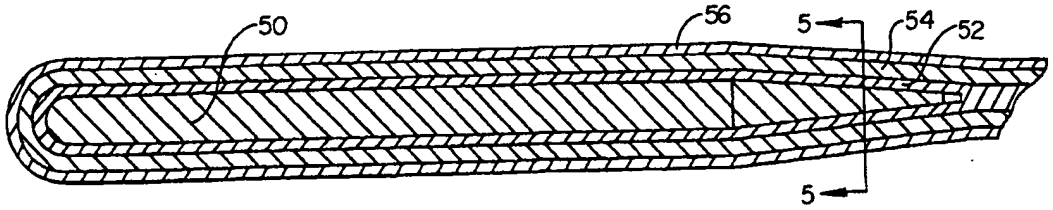

(57) Abstract

A multi-layered guide wire that uses separate layers (52, 54, 56) to achieve desired guide wire characteristics. Each of the layers may enhance one or more of the desired guide wire characteristics, with the combination of layers providing the desired combination of guide wire characteristics. Each of the layers may be provided over the entire guide wire (50), or only over selected portions of the guide wire. Further, selected layers may be co-extruded over the guide wire, which may reduce the manufacturing costs associated therewith.

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MULTI-LAYER GUIDE WIRE AND METHOD OF MANUFACTURE THEREFOR

Background of the Invention

The present invention relates to intravascular, gastrointestinal, or urological guide wires, and methods of manufacture therefor. In particular, the present invention relates to multi-layered intravascular guide wires, and methods of manufacture therefor.

Guide wires are used in various procedures in both the coronary regions and the peripheral regions of the body. Various sizes and lengths of guide wires are made to be suitable for various uses and locations in the body. For example, guide wires of very small diameters, on the order of 0.010 to 0.018 inches, may be suitable for use in narrow coronary vessels. Such guide wires may have an extremely floppy distal tip which may be bent or preformed by the physician to facilitate placement of the guide wire at the desired location. Other guide wires have a larger diameter, for example 0.035 inches, and preformed tip. These larger diameter guide wires may be especially useful in peripheral or gastrointestinal regions of the body. Larger diameter guide wires may be provided with very flexible tips or with relatively rigid tips depending upon the particular needs of the patient and the preferences of the physician. Guide wires come in a range of sizes in addition to those discussed above.

Some of the preferred characteristics in a guide wire include support, the ability to provide a track for a balloon or other device to advance over, and good torsional transmittance. A discussion of these and other preferred characteristics

of guide wires can be found in Endovascular Surgery, by Moore, W.S. and Ahn, S.S.; p. 157, W.B. Saunders Co. (1989). Other characteristics that are often desirable include flexibility, strength, radiopacity, color, lubricity, etc.

In many cases, providing a desired combination of guide wire characteristics can be a significant engineering challenge. In some cases, the approach used to enhance one guide wire characteristic may adversely affect another. For example, suppose a guide wire includes a plastic jacket around the distal tip of a guide wire core for support. The radiopacity of the guide wire tip may be enhanced by loading the plastic jacket with a high concentration of a radiopaque agent. However, by providing a high concentration of a radiopaque agent, the tensile strength of the plastic jacket is typically reduced. Thus, the strength of the distal tip of the guide wire is reduced, and the flexibility may be unduly increased. This illustrates the often difficult balance between competing characteristics of a typical guide wire design.

Summary of the Invention

The present invention provides a multi-layered guide wire that uses separate layers to achieve desired guide wire characteristics. Each of the layers may enhance one or more desired guide wire characteristics, with the combination of layers providing the desired combination of guide wire characteristics. Each of the layers may be provided over the entire guide wire, or only over selected portions of the guide wire. Further, selected layers may be co-extruded over the

guide wire, which may reduce the manufacturing costs associated with the multi-layer guide wire design.

In one illustrative embodiment of the present invention, a guide wire is provided that includes an elongated core with an outer axial surface. At least two outer jacket layers are co-extruded over at least a portion of the outer axial surface of the elongated core, and preferably over only the distal portion thereof. Each of the at least two outer jacket layers preferably have at least one physical property that differs from another one of the outer jacket layers. Illustrative physical properties include flexibility, radiopacity, strength, color, bonding characteristics, lubricity, etc.

In another illustrative embodiment of the present invention, a first and a second outer jacket layer are co-extruded over the distal end of the elongated core. The first outer jacket layer, which is disposed closest to the elongated core, may include a plastic that is loaded with a relatively high concentration of a radiopaque agent, such as tungsten, tantalum, platinum, gold, etc. This enhances the radiographic signature of the distal end of the guide wire. As indicated above, however, loading the first outer plastic jacket layer with a relatively high concentration of a radiopaque agent typically reduces the tensile strength thereof. To compensate for the reduced strength, the second outer jacket layer, which preferably has little or no radiopaque agent therein, is provided over the first outer plastic jacket. The combination of the first and second outer jacket layers provides a guide wire that has a highly radiopaque distal tip, and yet retains the desired strength characteristic.

In another illustrative embodiment, a first and a second outer jacket layer are co-extruded over selected portions of the elongated core. The term "selected portions" includes the entire elongated core, various sections of the elongated core, the distal tip or the core, etc. In this embodiment, the first outer jacket layer, which is disposed between the elongated core and the second outer jacket layer, is formed from a bonding material that is particularly suited for forming a bond between the second outer jacket layer and the elongated core. This provides an efficient method for bonding a plastic jacket to an elongated core, and in particular a metallic elongated core, without having to apply an adhesive or the like to the elongated core by conventional methods such as dipping or spraying. It has been found that this may reduce the cost of producing a guide wire that has one or more a plastic jacket layers thereon.

It is contemplated that the bonding layer may be co-extruded with any number of layers. For example, a guide wire may be formed by co-extruding a bonding layer, an inner plastic jacket and an outer plastic jacket over at least a portion of an elongated core. The inner plastic jacket may, for example, have a first concentration of a radiopaque agent, and the outer plastic jacket may have a second concentration of a radiopaque agent. The bonding layer preferably forms a bond between the elongated core and the inner plastic jacket. A lubricous layer may be co-extruding along with the bonding layer, the inner plastic jacket and the outer plastic jacket to provide a lubricous outer surface thereto.

Finally, and in another illustrative embodiment of the present invention, a number of outer jacket layers are co-extruded over a mandrel of the like to

produce a multi-layer tip assembly having a lumen. In one embodiment, the distal end of a guide wire is positioned in the lumen and the tip assembly is heated. By selecting the appropriate materials, the multi-layer tip assembly may shrink as a result of the heating process, securing the tip to the distal end of the guide wire. In another embodiment, a bonding adhesive may be used, wherein the bonding adhesive may be pressure activated or heat activated. Thus, the tip assembly may be secured to the distal tip of the guide wire by simply applying pressure or heat as appropriate.

Brief Description of the Drawings

Figure 1 is a cross-sectional side view of a first embodiment of the present invention;

Figure 2 is a cross-sectional view of the embodiment of Figure 1 taken along line 2-2;

Figure 3 is a cross-sectional view of the embodiment of Figure 1 taken along line 3-3;

Figure 4 is a cross-sectional side view of another embodiment of the present invention;

Figure 5 is a cross-sectional view of the embodiment of Figure 4 taken along line 5-5;

Figure 6 is a partial cross-sectional side view of a distal portion of yet another embodiment of the present invention; and

Figure 7 is a cross-sectional view of the embodiment of Figure 6 taken along line 7-7.

Detailed Description of the Preferred Embodiments

Referring to **Figure 1**, there is depicted a first illustrative embodiment of the present invention. This embodiment is an intravascular guide wire 10. The guide wire 10 is typically about 150-450 centimeters in length and has a typical outside diameter of approximately 0.035 inches. Other lengths and diameters may be provided so that a range of sizes of guide wires may be available suitable for the different needs of various individual patients and the preferences of physicians. Such other sizes are contemplated to be within the scope of the present invention and of this embodiment in particular.

The guide wire 10 includes a core wire 18 having a proximal end 12 and a distal end 14. The core wire may be made of a strong, yet flexible material, such as a metal like stainless steel, Nitinol, titanium, MP35N, Elgiloy™, or other materials, or combinations thereof. The distal end 14 may be shaped to provide a J-tip or other desired bend configuration. The J-tip configuration is shown in phantom lines 38.

In a preferred embodiment, the core wire 18 includes a distal portion 20 and a proximal portion 22. The proximal and distal portions are preferably formed of a single metallic wire. The distal portion 20 has a smaller cross section than the proximal portion 22 to impart greater flexibility to the distal end of the

guide wire 10. In a preferred embodiment, the distal portion 20 of the guide wire is tapered to impart increasing levels of flexibility to the guide wire toward the distal end 14. The tapered distal portion 20 preferably has a length of about 20 centimeters.

In the illustrative embodiment, the distal portion 20 has a distal tip portion 30. At least two outer jacket layers 32 and 34 are co-extruded over at least a portion of the distal tip portion 30, as shown. Each of the at least two outer jacket layers preferably has at least one physical property that differs from another one of the outer jacket layers. Illustrative physical properties include flexibility, radiopacity, strength, color, bonding characteristics, lubricity, etc.

In one illustrative embodiment, the first outer jacket layer 32, which is disposed closest to the elongated core wire 18, includes a PEBAX material that is loaded with a relatively high concentration of a radiopaque agent, such as at least about 50 percent by weight of tungsten, tantalum, platinum, or gold, and preferably 80 percent. This enhances the radiographic signature of the distal tip of the guide wire 10.

The relatively high concentration of tungsten tends to reduce the tensile strength of the plastic jacket 32. To compensate for this reduced strength, it is contemplated that the second outer jacket layer 34, which preferably is formed from PEBAX having little or no radiopaque agent therein, is provided over the first plastic jacket 32. In this configuration, the combination of the first outer jacket layer 32 and the second outer jacket layer 34 provides a guide wire 10 that has a highly radiopaque distal tip, and yet retains the desired strength

characteristic. The first and second outer jacket layers preferably extend a few millimeters distally of the distal end 14 of core wire 18 to provide a softer, more atraumatic distal tip to the guide wire 10.

The first outer jacket layer 32 may have a wall thickness in the range of about 0.002 to 0.008 inch, and the second outer jacket layer 34 may have a wall thickness in the range of about 0.001 to 0.002 inch. **Figure 2** shows a cross-section of the first outer jacket layer 32, the second outer jacket layer 34, and the core wire 18 taken along line 2-2 of **Figure 1**.

In another illustrative embodiment, the first outer jacket layer 32, which is disposed between the elongated core and the second outer jacket layer 34, is formed from a bonding material that is particularly suited for forming a bond between the second outer jacket layer 34 and the elongated core wire 18. It is contemplated that the bonding layer may be co-extruded with the second outer jacket layer 34. This provides an efficient method for bonding a plastic jacket 34 to an elongated core wire 18, and in particular a metallic elongated core, without having to apply an adhesive or the like to the elongated core wire 18 by conventional means such as dipping or spraying. Preferably, the bonding material is Plexar™ available from Quantum Chemical Corporation located in Cincinnati Ohio, Bynel™, EVA (Ethylene Vinyl Acetate), Urethane, Malaeic anhydride or a similar material of a category of extrudable adhesives used in extrusion and, in particular, those referred to as tie layers.

A Teflon® sleeve 40 may be provided over the core wire 18 proximal to the first and second outer jacket layers, as shown. The Teflon® sleeve 40 is preferably heat shrunk to the outer surface of the core wire 18 to provide a relatively lubricous surface thereto. **Figure 3** shows the Teflon® sleeve 40 placed around the proximal portion 22 of core wire 18.

It is also contemplated that a number of outer jacket layers may be co-extruded over a mandrel of the like to produce a multi-layer tip assembly having a lumen. In one embodiment, the distal end of a guide wire is positioned in the lumen and the tip assembly is heated. By selecting the appropriate materials, the multi-layer tip assembly may shrink as a result of the heating process, securing the tip to the distal end of the guide wire. In another embodiment, a bonding adhesive may be used, wherein the bonding adhesive may be pressure activated or heat activated. Thus, the tip assembly may be secured to the distal tip of the guide wire by simply applying pressure or heat as appropriate.

Figure 4 is a cross-sectional side view of another embodiment of the present invention. In this embodiment, a number of outer jacket layers are co-extruded over the entire length of a core wire 50. Although the outer jacket layers are shown extending the entire length of the core wire 50, it is contemplated that the outer jacket layers may be provided only over selected sections of the core wire 50.

In the illustrative embodiment, a bonding layer 52 is co-extruded with any number of layers including an inner plastic jacket layer 54 and an outer plastic

jacket layer 56. As noted above, the inner plastic jacket layer 54 may, for example, have a first concentration of a radiopaque agent, and the outer plastic jacket layer 56 may have a second concentration of a radiopaque agent. The bonding layer may form a bond between the elongated core 50 and the inner plastic jacket layer 52. The inner and outer plastic jacket layers 54 and 56 are preferably formed from similar materials so that a bond is formed therebetween during the co-extrusion process.

It is contemplated a lubricous layer may also be co-extruding with the bonding layer, the inner plastic jacket and the outer plastic jacket to provide a lubricous outer surface thereto. The lubricous layer may be a hydrophilic coating such as Union Carbide Polyslip™ P106 and T503M, or a coating similar to that described in U.S. Patent No. 5,702,754 to Zong. Some thermoplastic urethane materials may provide a hydrophilic coating that is extrudable. Alternatively, the lubricous layer may be applied by dipping or spraying, as is known in the art.

An advantage of using a hydrophilic coating is that the guide wire and/or guide wire tip may be used to deliver drugs or the like to the treated vessel. Hydrophilic coatings are effective for absorbing liquids, including liquid drugs. When the hydrophilic coating absorbed a drug, such as heparin for example, and later comes into contact with a vessel wall or the like, some of the absorbed drug is delivered to the vessel wall. Thus, it is contemplated that the hydrophilic coating may be a drug coating.

Figure 5 is a cross-sectional view of the embodiment of **Figure 4** taken along line 5-5 showing a bonding layer 52 that is co-extruded with an inner plastic jacket layer 54 and an outer plastic jacket layer 56 over core wire 50. In the illustrative embodiment, the bonding layer 52 and the outer plastic jacket layer 56 are thinner than the inner plastic jacket layer 54. When the inner plastic jacket layer 54 is loaded with a high concentration of a radiopaque agent, this configuration may provide the maximum radiopacity to the distal tip of the guide wire, while maintaining the other desired characteristics of the guide wire.

Figure 6 is a partial cross-sectional side view of a distal portion of yet another embodiment of the present invention. In this illustrative embodiment, a bonding layer 70, an inner plastic jacket layer 72, an outer plastic jacket layer 74 and a lubricous layer 76 are all co-extruded over a core wire 80. The bonding layer 70 preferably forms a bond between the elongated core wire 80 and the inner plastic jacket layer 72. The inner and outer plastic jacket layers 72 and 74 are preferably formed from similar materials so that a bond is formed therebetween during the co-extrusion process. The lubricous layer may be an extrudable hydrophilic coating that bonds to the outer plastic jacket 74.

Figure 7 is a cross-sectional view of the embodiment of **Figure 6** taken along line 7-7. In the illustrative embodiment, the bonding layer 70 and the outer plastic jacket layer 74 are thinner than the inner plastic jacket layer 72. When the inner plastic jacket layer 72 is loaded with a relatively high concentration of a radiopaque agent, for example, this configuration may provide the maximum

radiopacity to the distal tip of the guide wire, while maintaining the other desired characteristics of the guide wire.

It is intended that the foregoing detailed description be regarded as illustrated rather than limiting and that it is understood that the following claims including all equivalents are intended to define the scope of the invention.

What is claimed is:

1. A method for making a guide wire having an elongated core with an outer axial surface, the method comprising the steps of:

co-extruding at least two outer jacket layers over at least a portion of said outer axial surface of said elongated core, wherein one of the outer jacket layers has at least one physical property that is different from another one of the outer jacket layers.

2. A method according to claim 1 wherein the at least one physical property is selected from the group consisting of radiopacity, strength, color, bonding characteristics, and lubricity.

3. A method according to claim 1 wherein two outer jacket layers are co-extruded over at least a portion of said outer axial surface of said elongated core.

4. A method according to claim 3 wherein a first one of the two outer jacket layers is disposed closer to the elongated core than a second one of the two outer jacket layers, and said first outer jacket layer comprising a plastic with a concentration of a radiopaque agent therein, said second outer jacket layer comprising a plastic with substantially no radiopaque agent therein.

5. A method according to claim 4 wherein the concentration of the radiopaque agent in the first outer jacket is at least about 50 percent by weight.

6. A method according to claim 4 wherein the radiopaque agent is selected from the group consisting of tungsten, tantalum, platinum and gold.

7. A method according to claim 3 wherein a first one of the two outer jacket layers is disposed between the elongated core and a second one of the two outer jacket layers, said first outer jacket layer comprising a bonding material that bonds the second outer jacket layer to the elongated core.

8. A method according to claim 7 wherein the bond material is selected from the group consisting of Plexar™, Bynel™, EVA (Ethylene Vinyl Acetate), Urethane, and Malaeic anhydride.

9. A method according to claim 1 wherein the at least two outer jacket layers collectively have a wall thickness, wherein one of the at least two outer jacket layers comprises a majority of the wall thickness.

10. A method according to claim 9 wherein the outer jacket layer that comprises a majority of the wall thickness includes a radiopaque agent.

11. A method according to claim 1 wherein the at least two outer jacket layers are co-extruded over only a distal portion of said outer axial surface of said elongated core.

12. A method for forming a guide wire having an elongated core, the method comprising the steps of:

co-extruding a bonding layer and a plastic jacket over at least a portion of the elongated core, wherein the bonding layer forms a bond between the elongated core and the plastic jacket.

13. A method according to claim 12 wherein a lubricous layer is co-extruding along with the bonding layer, the inner plastic jacket and the outer plastic jacket.

14. A method for forming a guide wire having an elongated core, the method comprising the steps of:

co-extruding a bonding layer, an inner plastic jacket and an outer plastic jacket over at least a portion of the elongated core, wherein the inner plastic jacket has a first concentration of a radiopaque agent, and said outer plastic jacket has a second concentration of a radiopaque agent, wherein the first concentration is greater than the second concentration, said bonding layer forming a bond between the elongated core and the inner plastic jacket.

15. A method according to claim 14 wherein a lubricous layer is co-extruding along with the bonding layer, the inner plastic jacket and the outer plastic jacket.

16. A method according to claim 14 wherein the first concentration is at least about 50 percent by weight, and the second concentration is substantially zero.

17. A guide wire comprising:

an elongated core having an outer axial surface;

at least two jacket layers co-extruded over at least a portion of said outer axial surface of said elongated core, wherein one of the jacket layers has at least one physical property that is different from another one of the jacket layers.

18. A method according to claim 17 wherein the at least one physical property is selected from the group consisting of radiopacity, strength, color, bonding characteristics, and lubricity.

19. A guide wire comprising:

an elongated core having an outer axial surface;

an inner plastic jacket extending around a selected portion of said outer axial surface of said elongated core, said inner plastic jacket having a first

concentration of a radiopaque agent for enhancing the radiopaque properties of the inner plastic jacket;

an outer plastic jacket extending around at least a portion of said inner plastic jacket, said outer plastic jacket having a second concentration of a radiopaque agent, wherein the second concentration is less than the first concentration; and

said inner plastic jacket and said outer plastic jacket being co-extruded over the selected portion of said outer axial surface of said elongated core.

20. A guide wire according to claim 19 wherein said inner plastic jacket is formed from PEBAX, and the radiopaque agent is tungsten.

21. A guide wire according to claim 20 wherein the first concentration is at least about 50 percent by weight.

22. A guide wire according to claim 21 wherein said outer plastic jacket is formed from PEBAX.

23. A guide wire according to claim 22 wherein the second concentration is substantially zero.

24. A guide wire according to claim 19 further comprising a lubricous outer layer extending around at least a portion of said outer plastic jacket, wherein

said inner plastic jacket, said outer plastic jacket, and said lubricous outer layer are co-extruded over said elongated core.

25. A guide wire according to claim 19 further comprising:

a bonding layer interposed between said elongated core and said inner plastic jacket for providing a bond therebetween.

26. A guide wire according to claim 25 wherein said bonding layer and said inner plastic jacket are co-extruded over said elongated core.

27. A guide wire according to claim 26 wherein said bonding layer comprises a material selected from the group consisting of Plexar™, Bynel™, EVA (Ethylene Vinyl Acetate), Urethane, and Malaeic anhydride.

28. A guide wire according to claim 27 wherein said elongated core comprises a material selected from the group consisting of Nitinol, stainless steel, titanium, MP35N, and Elgiloy™.

29. A guide wire according to claim 27 wherein said elongated core is formed from stainless steel.

30. A guide wire according to claim 25 wherein said bonding layer, said inner plastic jacket, and said outer plastic jacket are co-extruded over said elongated core.

31. A guide wire according to claim 24 further comprising a bonding layer interposed between said elongated core and said inner plastic jacket for providing a bond therebetween, wherein said bonding layer, said inner plastic jacket, said outer plastic jacket, and said lubricous outer layer are co-extruded over said elongated core.

32. A guide wire according to claim 24 wherein said lubricous outer layer comprises a hydrophilic coating.

33, A guide wire according to claim 32 wherein the hydrophilic coating contains a drug, thereby forming a drug coating.

34. A guide wire according to claim 24 wherein the lubricous outer layer comprises a thermoplastic urethane material.

35. A guide wire according to claim 19 wherein said inner plastic jacket extends around only a distal portion of said outer axial surface of said elongated core.

36. A guide wire according to claim 35 wherein a sleeve extends around a proximal portion of said outer axial surface of said elongated core.

37. A guide wire according to claim 36 wherein the sleeve comprises polytetrafluoroethylene (TEFLON).

38. A method for making a guide wire tip for a core wire having a distal end, the method comprising the steps of:

co-extruding at least two outer jacket layers to form a guide wire tip, the guide wire tip having a lumen extending at least partially therethrough, and at least one of said at least two outer jacket layers formed from a material that shrinks when subject to heat;

inserting the distal end of the core wire into the lumen of the guide wire tip;

heating the guide wire tip to secure the guide wire tip to the core wire.

39. A method according to claim 38 wherein one of the outer jacket layers has at least one physical property that is different from another one of the outer jacket layers.

40. A method according to claim 39 wherein the at least one physical property is selected from the group consisting of radiopacity, strength, color, bonding characteristics, heat shrink characteristics, and lubricity.

41. A method for making a guide wire tip for a core wire having a distal end, the method comprising the steps of:

co-extruding at least two outer jacket layers to form a guide wire tip, the guide wire tip having a lumen extending at least partially therethrough;

providing a pressure sensitive adhesive between the core wire and the guide wire tip;

inserting the distal end of the core wire into the lumen of the guide wire tip;

applying pressure to the guide wire tip to activate the pressure sensitive adhesive to secure the guide wire tip to the core wire.

42. A method according to claim 41 wherein the pressure sensitive adhesive is one of the at least two outer layers.

43. A method according to claim 41 wherein the pressure sensitive adhesive is applied to the distal end of the core wire.

44. A method according to claim 41 wherein the pressure sensitive adhesive is applied to the lumen of the guide wire tip.

45. A method for making a guide wire tip for a core wire having a distal end, the method comprising the steps of:

co-extruding at least two outer jacket layers to form a guide wire tip, the guide wire tip having a lumen extending at least partially therethrough;

providing a heat activated adhesive between the core wire and the guide wire tip;

inserting the distal end of the core wire into the lumen of the guide wire tip;

applying heat to the guide wire tip to activate the heat activated adhesive to secure the guide wire tip to the core wire.

46. A method according to claim 45 wherein the heat activated adhesive is one of the at least two outer layers.

47. A method according to claim 45 wherein the heat activated adhesive is applied to the distal end of the core wire.

48. A method according to claim 45 wherein the heat activated adhesive is applied to the lumen of the guide wire tip.

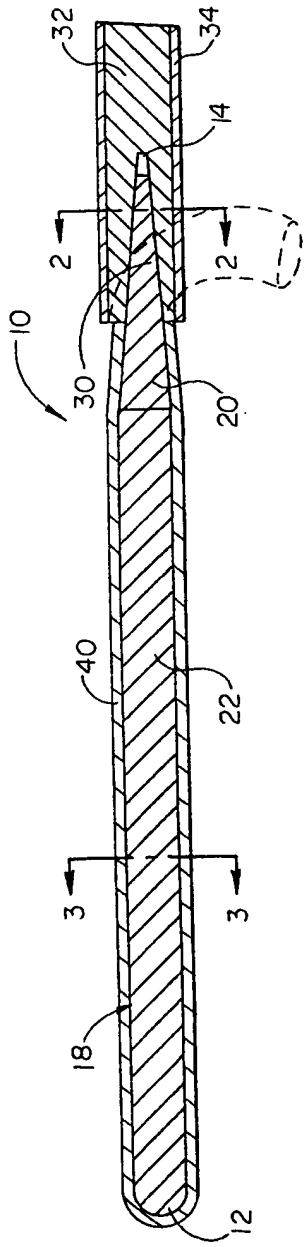

Fig. 1

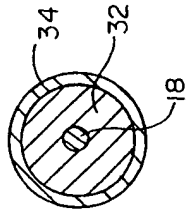

Fig. 2

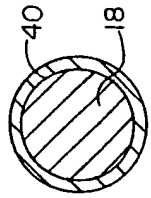

Fig. 3

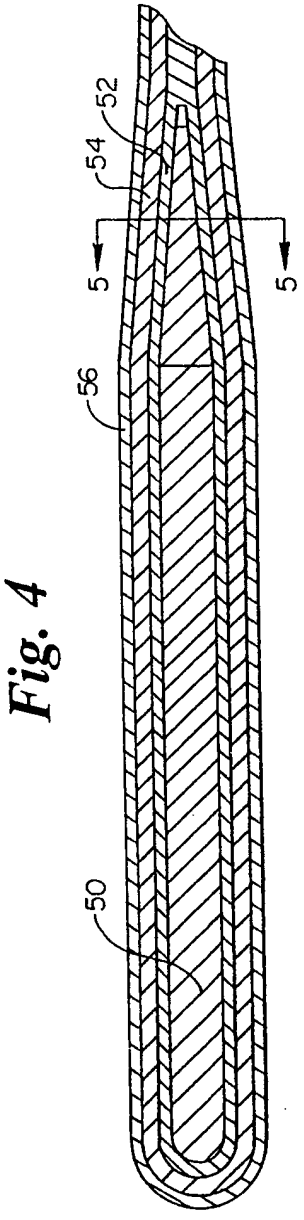

Fig. 4

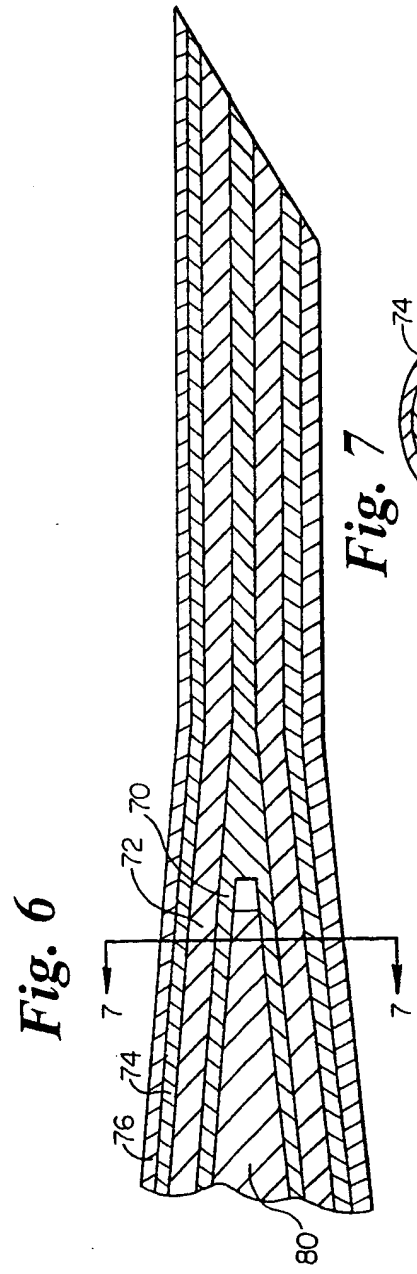

Fig. 6

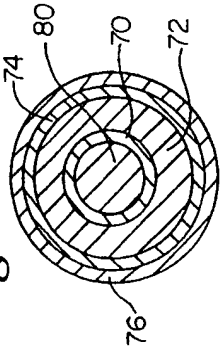

Fig. 7

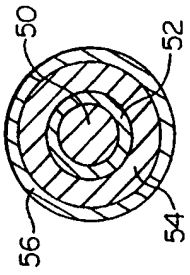

Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/05417

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :B29C 47/06
US CL : 264/173.12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 156/244.12, 500; 264/171.14, 171.17, 173.12, 173.16; 600/585

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,333,620 A (MOUTAFIS et al) 02 August 1994, entire document.	1-16
Y	US 4,867,174 A (SKRIBISKI) 19 September 1989, Fig. 2.	1-16
Y	EP 407 965 A1 (TERUMO KABUSHIKI KAISHA) 16 January 1991, page 3.	1-16
Y	US 5,681,514 A (WOODY), 28 October 1997, abstract.	1-16
Y	US 5,716,574 A (KAWASAKI), 10 February 1998, abstract.	1-16
Y	US 4,250,072 A (FLYNN) 10 February 1981, col. 7, lines 5-60.	14-16

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 16 APRIL 1999	Date of mailing of the international search report 26 MAY 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MICHAEL BALL BRIAN A. HARDEN PARALEGAL SPECIALIST GROUP 700 Telephone No. (703) 308-0661

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/05417

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,095,915 A (ENGELSON) 17 March 1992, abstract.	11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/05417

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING
This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claims 1-16, drawn to a method for making a guide wire.
Group II, claims 17-37, drawn to a guide wire.
Group III, claims 38-48, drawn to a method for making a guide wire tip.
The inventions listed as Groups I-III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the inventions listed as Groups I-III each comprise the co-extrusion of at least two layers having different physical properties. However, this technical feature does not define a contribution over the prior art since co-extrusion of layers with different physical properties is known in the art as evidenced by either US 5,716,574 or US 5,681,514.